



# Senate

General Assembly

**File No. 468**

February Session, 2010

Substitute Senate Bill No. 270

*Senate, April 12, 2010*

The Committee on Public Health reported through SEN. HARRIS of the 5th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

***AN ACT CONCERNING THE PROHIBITION OF CERTAIN GIFTS  
FROM PHARMACEUTICAL AND MEDICAL DEVICE  
MANUFACTURING COMPANIES TO HEALTH CARE PROVIDERS.***

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective July 1, 2010*) As used in sections 1 to 7,  
2 inclusive, of this act:

3 (1) "Biologic" means a "biological product", as defined in 42 USC  
4 262(i), as amended from time to time, that is regulated as a drug under  
5 the federal Food, Drug and Cosmetic Act, 21 USC 301 et seq.;

6 (2) "Bona fide services" means an arrangement for services  
7 including, but not limited to: (A) Research, (B) participation on  
8 advisory boards, (C) collaboration with nonprofit organizations, as  
9 described in Section 501(c)(3) of the Internal Revenue Code of 1986, or  
10 any subsequent corresponding internal revenue code of the United  
11 States, as from time to time amended, that are dedicated to the  
12 promotion of health and the prevention of disease, and (D)

13 presentations at pharmaceutical or medical device manufacturing  
14 company-sponsored medical education and training, including the  
15 federal Food and Drug Administration required education and  
16 training involved in producing safe and effective medical devices,  
17 provided such arrangement is formalized in a written agreement  
18 specifying the services to be provided, based on the fair market value  
19 of the services and characterized by the following factors: (i) A  
20 legitimate need for the services clearly identified in advance; (ii) a  
21 connection between the competence and expertise of the health care  
22 provider and the purpose of the arrangement; (iii) the number of  
23 health care providers retained is not greater than the number  
24 reasonably necessary to achieve the identified purpose; (iv) the  
25 retaining pharmaceutical or medical device manufacturing company  
26 maintains records concerning the arrangement and makes appropriate  
27 use of the services provided by the health care provider; (v) the venue  
28 and circumstances of any meeting with the health care provider is  
29 conducive to the services and activities related to the services are the  
30 primary focus of the meeting; and (vi) the decision to retain a health  
31 care provider is not unduly influenced by a pharmaceutical or medical  
32 device manufacturing company's sales personnel;

33 (3) "Charitable donation" means the provision of financial support  
34 to a nonprofit organization, as described in Section 501(c)(3) of the  
35 Internal Revenue Code of 1986, or any subsequent corresponding  
36 internal revenue code of the United States, as from time to time  
37 amended or the in-kind provision of prescription drugs, biologics or  
38 medical devices for charity care of patients;

39 (4) "Conference" or "meeting" means any convening where  
40 responsibility for and control over the selection of content, faculty,  
41 educational methods, materials and venue belong to the event's  
42 organizers in accordance with their guidelines, held in a venue that is  
43 appropriate and conducive to informational communication and  
44 training about medical information, where (A) the gathering is  
45 primarily dedicated, in both time and effort, to promoting objective  
46 scientific and educational activities and discourse and one or more

47 educational presentations are the primary reason for the gathering,  
48 and (B) the main purpose for bringing attendees together is to further  
49 their knowledge on the topic or topics being presented;

50 (5) "Covered recipient" means a person authorized to prescribe,  
51 dispense or purchase prescription drugs or medical devices in this  
52 state, including a hospital, nursing home, pharmacist, health benefit  
53 plan administrator or a health care provider. "Covered recipient" does  
54 not include a bona fide employee of a pharmaceutical or medical  
55 device manufacturing company or a consumer who purchases  
56 prescription drugs or medical devices;

57 (6) "Department" means the Department of Consumer Protection;

58 (7) "Health care provider" means a person who prescribes  
59 prescription drugs for any person and is licensed to provide health  
60 care in this state, or a partnership or corporation comprised of such  
61 persons, or an officer, employee, agent or contractor of such person  
62 acting in the course and scope of his employment, agency or contract  
63 related to or in support of the provision of health care to individuals.  
64 "Health care provider" does not include hospitals and full-time  
65 employees and members of the board of directors of pharmaceutical or  
66 medical device manufacturers;

67 (8) "Hospital setting" means (A) a hospital, (B) academic medical  
68 center, or (C) pharmaceutical or medical device specialized training  
69 facility, where the facility, as certified by the pharmaceutical or  
70 medical device manufacturing company to the Department of  
71 Consumer Protection, is specifically designed to (i) approximate the  
72 conditions of a surgical suite or a working clinical laboratory; or (ii)  
73 provide medical training on large or technical medical devices, such as  
74 surgical equipment, implants and imaging and clinical laboratory  
75 equipment;

76 (9) "Medical device" means an instrument, apparatus, implement,  
77 machine, contrivance, implant, in vitro reagent or other similar or  
78 related article, including any component, part or accessory, that is: (A)

79 Recognized in the official National Formulary or the United States  
80 Pharmacopeia or any supplement thereto; (B) intended for use in the  
81 diagnosis of disease or other conditions or in the cure, mitigation,  
82 treatment or prevention of disease, in persons or animals; or (C)  
83 intended to affect the structure or function of the body of a person or  
84 animal, and that does not achieve its primary intended purposes  
85 through chemical action within or on such body and that is not  
86 dependent upon being metabolized for the achievement of its primary  
87 intended purposes;

88 (10) "Nonfaculty" means a health care provider who does not serve  
89 as a speaker or provide actual and substantive services as a faculty  
90 organizer or academic program consultant for a continuing medical  
91 education event, third-party scientific or educational conference or  
92 professional meeting;

93 (11) "Person" means a business, individual, corporation, union,  
94 association, firm, partnership, committee or other organization;

95 (12) "Pharmaceutical or medical device manufacturer agent" means  
96 a person who, while employed by or under contract with a  
97 pharmaceutical or medical device manufacturing company, engages in  
98 detailing, promotional activities or other marketing of prescription  
99 drugs, biologics or medical devices in this state to any physician,  
100 hospital, nursing home, pharmacist, health benefits plan administrator,  
101 other health care provider or person authorized to prescribe, dispense  
102 or purchase prescription drugs, biologics or medical devices.  
103 "Pharmaceutical or medical device manufacturer agent" does not  
104 include: (A) A licensed pharmacist, (B) a licensed physician or any  
105 other licensed health care provider with authority to prescribe  
106 prescription drugs, biologics or medical devices who is acting within  
107 the ordinary scope of the practice for which he or she is licensed, (C) a  
108 wholesale drug distributor registered with the department pursuant to  
109 section 21a-70 of the general statutes, (D) a representative of such  
110 distributor who promotes or otherwise markets the services of the  
111 wholesale drug distributor in connection with a prescription drug, or

112 (E) a retail pharmacy licensed in this state, provided such person is not  
113 engaging in such practices while employed by or under contract with a  
114 pharmaceutical or medical device manufacturing company;

115 (13) "Pharmaceutical or medical device manufacturing company"  
116 means any entity that: (A) Is engaged in the production, preparation,  
117 propagation, compounding, conversion or processing of prescription  
118 drugs, biologics or medical devices, either directly or indirectly, by  
119 extraction from substances of natural origin or independently by  
120 means of chemical synthesis or by a combination of extraction and  
121 chemical synthesis; or (B) is directly engaged in the packaging,  
122 repackaging, labeling, relabeling or distribution of prescription drugs,  
123 biologics or medical devices. "Pharmaceutical or medical device  
124 manufacturing company" does not include a health care provider,  
125 physician practice, home health agency, hospital licensed in this state,  
126 wholesale drug distributor licensed in this state or a retail pharmacy  
127 licensed in this state; and

128 (14) "Prescription drugs" means drugs upon which the  
129 manufacturer or distributor has placed or is required by federal law  
130 and regulations to place the following or a comparable warning:  
131 "Caution: Federal law prohibits dispensing without prescription".

132 Sec. 2. (NEW) (*Effective July 1, 2010*) (a) Each pharmaceutical or  
133 medical device manufacturing company that employs or contracts  
134 with a pharmaceutical or medical device manufacturer agent shall: (1)  
135 Adopt a marketing code of conduct in compliance with the provisions  
136 of sections 1 to 7, inclusive, of this act; (2) on or before July 1, 2011, and  
137 annually thereafter, submit to the department a copy of its marketing  
138 code; and (3) on or before July 1, 2011, and annually thereafter, submit  
139 to the department a description of its training program to provide  
140 regular training to appropriate employees including, but not limited  
141 to, all sales and marketing staff, on the marketing code of conduct. The  
142 training program shall ensure that all representatives who are  
143 employed by or acting on behalf of a pharmaceutical or medical device  
144 manufacturing company and who visit health care providers have

145 sufficient knowledge of the marketing code of conduct, general science  
146 and product-specific information in order to provide accurate, up-to-  
147 date information, consistent with state law and federal Food and Drug  
148 Administration requirements. The training program shall also provide  
149 for regular assessments of persons who are employed by or acting on  
150 behalf of the company to ensure that such persons comply with the  
151 provisions of sections 1 to 7, inclusive, of this act and other relevant  
152 company policies.

153 (b) In addition to the requirements prescribed in subsection (a) of  
154 this section, on or before July 1, 2011, and annually thereafter, each  
155 pharmaceutical or medical device manufacturing company that  
156 employs or contracts with a pharmaceutical or medical device  
157 manufacturer agent shall (1) certify to the department, to the best of  
158 the company's knowledge, information and belief that it is in  
159 compliance with the provisions of sections 1 to 7, inclusive, of this act;  
160 (2) submit to the department policies and procedures for investigating  
161 noncompliance with the provisions of sections 1 to 7, inclusive, of this  
162 act, taking corrective action in response to noncompliance and  
163 reporting instances of noncompliance to the appropriate state  
164 authorities; and (3) submit to the department the name, title, address,  
165 telephone number and electronic mail address of the compliance  
166 officer it has identified as responsible for certifying compliance with  
167 the provisions of sections 1 to 7, inclusive, of this act and  
168 implementing, monitoring and enforcing the company's marketing  
169 code of conduct.

170 (c) Each pharmaceutical or medical device manufacturing company  
171 that uses prescriber data unrelated to the identity of a patient to  
172 facilitate communications with health care providers shall (1) maintain  
173 the confidential nature of prescriber data; (2) develop policies  
174 regarding the use of the data; (3) educate company employees and  
175 pharmaceutical or medical device manufacturer agents concerning  
176 such policies and designate an internal contact person to handle  
177 inquiries regarding the use of the data; (4) identify appropriate  
178 disciplinary actions for misuse of the data; and (5) comply with the

179 request of any health care provider who requests that prescriber data  
180 not be made available to company sales representatives. Prior to  
181 utilizing health care provider prescriber data for marketing purposes,  
182 a pharmaceutical or medical device manufacturing company shall give  
183 health care providers the opportunity to request that their prescriber  
184 data be withheld from company sales representatives and not be used  
185 for marketing purposes.

186 (d) Nothing in subsection (c) of this section shall prohibit  
187 pharmaceutical or medical device manufacturing companies from  
188 using prescriber data to impart important safety and risk information  
189 to prescribers of a particular drug or device, conduct research, comply  
190 with federal Food and Drug Administration mandated risk  
191 management plans that require manufacturers to identify and interact  
192 with health care providers who prescribe certain drugs or devices or  
193 track adverse events of marketed prescription drugs, biologics or  
194 devices.

195 (e) In all speaker and commercial consultant contracts,  
196 pharmaceutical or medical device manufacturing companies shall  
197 require any health care provider who is a member of a committee that  
198 sets formularies or develops clinical guidelines and also serves as a  
199 speaker or commercial consultant for the company to disclose to the  
200 committee the nature and existence of the provider's relationship with  
201 the company. The disclosure requirement shall extend for not less than  
202 two years following the date of the termination of any speaker or  
203 consultant arrangement.

204 (f) Not later than July 1, 2011, and annually thereafter, each  
205 pharmaceutical and medical device manufacturing company shall  
206 certify to the department that the company has external verification  
207 procedures in place to monitor compliance with the provisions of  
208 sections 1 to 7, inclusive, of this act.

209 Sec. 3. (NEW) (*Effective July 1, 2010*) (a) Except as provided in  
210 sections 4 and 5 of this act, no pharmaceutical or medical device  
211 manufacturing company that employs or contracts with a

212 pharmaceutical or medical device manufacturer agent may provide or  
213 pay for meals for health care providers that are (1) part of an  
214 entertainment or recreational event; (2) offered without an  
215 informational presentation made by a pharmaceutical or medical  
216 device marketing agent or without such an agent being present; (3)  
217 offered, consumed or provided outside of the health care provider's  
218 office or a hospital setting; or (4) provided to a healthcare provider's  
219 spouse or other guest.

220 (b) Meals provided to health care providers that are otherwise in  
221 compliance with the provisions of subsection (a) of this section shall be  
222 modest and occasional in nature.

223 Sec. 4. (NEW) (*Effective July 1, 2010*) (a) No pharmaceutical or  
224 medical device manufacturing company that employs or contracts  
225 with a pharmaceutical or medical device manufacturer agent may  
226 provide: (1) Financial support for the costs of travel, lodging or other  
227 personal expenses of nonfaculty health care providers attending any  
228 continuing medical education event, third-party scientific or  
229 educational conference or professional meetings, either directly to the  
230 individuals participating in the event or indirectly to the event's  
231 sponsor; (2) funding to compensate for the time spent by health care  
232 providers participating in any continuing medical education event,  
233 third-party scientific or educational conferences or professional  
234 meetings; (3) payment for meals directly to a health care provider at  
235 any continuing medical education event, third-party scientific or  
236 educational conferences or professional meetings, except that a  
237 continuing medical education provider or conference or meeting  
238 organizer may, at its own discretion, apply any financial support  
239 provided by a pharmaceutical or medical device manufacturing  
240 company for the event to provide meals for all participants; or (4)  
241 sponsorship or payment for continuing medical education or  
242 independent medical education, that does not meet the Standards for  
243 Commercial Support as established by the Accreditation Council for  
244 Continuing Medical Education or equivalent commercial support  
245 standards of the relevant continuing education accrediting body.

246 (b) A pharmaceutical or medical device manufacturing company  
247 shall separate its continuing medical education grant-making functions  
248 from its sales and marketing divisions.

249 (c) A pharmaceutical or medical device manufacturing company  
250 shall not provide any advice or guidance to the continuing medical  
251 education provider regarding the content or faculty for a particular  
252 continuing medical education program funded by the company.

253 (d) Nothing in sections 1 to 7, inclusive, of this act shall prohibit: (1)  
254 Compensation or reimbursement made to a health care provider  
255 serving as a speaker or providing actual and substantive services as a  
256 faculty organizer or academic program consultant for a continuing  
257 medical education event, third-party scientific or educational  
258 conference or professional meeting, provided the payment is  
259 reasonable, based on fair market value and complies with the  
260 standards for commercial support as established by the relevant  
261 accreditation entity; (2) sponsorship or payment for any portion of a  
262 third-party scientific or educational conference, charitable conference  
263 or meeting or professional meeting, where the payment is made  
264 directly to the conference or meeting organizers; or (3) the use of hotel  
265 facilities, convention center facilities or other special event venues for  
266 continuing medical education or other third-party scientific,  
267 educational or professional meetings or conferences.

268 Sec. 5. (NEW) (*Effective July 1, 2010*) (a) No pharmaceutical or  
269 medical device manufacturing company that employs or contracts  
270 with a pharmaceutical or medical device manufacturer agent may  
271 provide: (1) Entertainment or recreational items of any value,  
272 including, but not limited to, tickets to the theater, concerts or sporting  
273 events, sporting equipment or leisure or vacation trips, to any health  
274 care provider who is not a salaried employee of the pharmaceutical or  
275 medical device manufacturing company; (2) payments of any kind,  
276 including cash or cash equivalents, equity, in kind or tangible items,  
277 including any complimentary items such as pens, coffee mugs or gift  
278 cards to health care providers either directly or indirectly, except as

279 compensation for bona fide services; or (3) any grants, scholarships,  
280 subsidies, supports, consulting contracts or educational or practice  
281 related items in exchange for prescribing, disbursing or using  
282 prescription drugs, biologics or medical devices or for a commitment  
283 to continue prescribing, disbursing or using prescription drugs,  
284 biologics or medical devices.

285 (b) Nothing in this section shall prohibit: (1) Reasonable  
286 compensation for bona fide services or the reimbursement of other  
287 reasonable out-of-pocket costs incurred by the health care provider  
288 directly as a result of the performance of such services, where the  
289 compensation and reimbursement is specified in, and paid for under, a  
290 written agreement; (2) payment or reimbursement for the reasonable  
291 expenses, including travel and lodging-related expenses necessary for  
292 technical training of health care providers on the use of a medical  
293 device if the commitment to provide such expenses and the amounts  
294 or categories of reasonable expenses to be paid are described in the  
295 written agreement between the health care provider and the device  
296 vendor for the purchase of the device; (3) the provision of items that  
297 are designed for the education of health care providers, such as  
298 pamphlets, brochures and posters, provided the value of such items  
299 does not exceed one hundred dollars and such items have no value to  
300 the health care provider outside of his or her professional  
301 responsibility; (4) the provision, distribution, dissemination or receipt  
302 of peer reviewed academic, scientific or clinical information; (5) the  
303 purchase of advertising in peer reviewed academic, scientific or  
304 clinical journals; (6) the provision of prescription drugs to a health care  
305 provider solely and exclusively for use by the health care provider's  
306 patients; (7) the provision of reasonable quantities of medical device  
307 demonstration and evaluation units provided to a health care provider  
308 to assess the appropriate use and functionality of the product and  
309 determine whether or not and when to use or recommend the product  
310 in the future; (8) the provision of medical text books or anatomical  
311 models that are designed for the education of health care providers; (9)  
312 the provision of price concessions, such as rebates or discounts, in the  
313 normal course of business; (10) the provision of reimbursement

314 information regarding products, including (A) identifying appropriate  
315 coverage, coding or billing of products, (B) procedures for using such  
316 products and information, in support of accurate and responsible  
317 billing to Medicare and other payors, and (C) information designed to  
318 offer technical or other support intended to aid in the appropriate and  
319 efficient use or installation of products, except that such technical or  
320 other support shall not be offered or provided for the purpose of  
321 inducing health care providers to purchase, lease, recommend, use or  
322 arrange for the purchase, lease or prescription of such products; (11)  
323 the provision of payments or the provision of free outpatient  
324 prescription drugs to health care providers for the benefit of low  
325 income individuals, through established patient assistance programs,  
326 provided the program meets the criterion for a permissible program in  
327 accordance with the relevant published guidance available from the  
328 Office of the Inspector General of the United States Department of  
329 Health and Human Services, or is otherwise permitted under  
330 applicable federal laws and regulations including, but not limited to,  
331 42 USC 1320a-7b; or (12) the provision of charitable donations  
332 provided the donation (A) is not provided in exchange for prescribing,  
333 disbursing or using prescription drugs, biologics or medical devices or  
334 for a commitment to continue prescribing, disbursing or using  
335 prescription drugs, biologics or medical devices, and (B) does not  
336 otherwise violate the provisions of sections 1 to 7, inclusive, of this act.

337       Sec. 6. (NEW) (*Effective July 1, 2010*) No pharmaceutical or medical  
338 device manufacturing company shall discharge, refuse to hire, refuse  
339 to serve or in any manner retaliate or take any adverse action against  
340 any employee, applicant, health care provider or covered recipient if  
341 such employee, applicant, health care provider or covered recipient  
342 takes or has taken any action in furtherance of the enforcement of the  
343 provisions of sections 1 to 7, inclusive, of this act.

344       Sec. 7. (NEW) (*Effective July 1, 2010*) (a) A person who knowingly  
345 and wilfully violates any provision of sections 2 to 6, inclusive, of this  
346 act shall be liable for a civil fine of not more than five thousand dollars  
347 for each transaction, occurrence or event that constitutes a violation of

348 sections 2 to 6, inclusive, of this act.

349 (b) The Department of Consumer Protection may assess a civil fine  
350 in accordance with the provisions of subsection (a) of this section.  
351 Upon request of the Commissioner of Consumer Protection, the  
352 Attorney General may petition the superior court for collection of such  
353 fine and such equitable and injunctive relief as the court deems  
354 appropriate.

This act shall take effect as follows and shall amend the following sections:		
Section 1	July 1, 2010	New section
Sec. 2	July 1, 2010	New section
Sec. 3	July 1, 2010	New section
Sec. 4	July 1, 2010	New section
Sec. 5	July 1, 2010	New section
Sec. 6	July 1, 2010	New section
Sec. 7	July 1, 2010	New section

**Statement of Legislative Commissioners:**

In section 1, the definitions of "Clinical trial" and "Genuine research project" were removed for accuracy as the substitute bill removed the only section of the bill that used these terms.

**PH** Joint Favorable Subst.

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

**OFA Fiscal Note**

**State Impact:**

Agency Affected	Fund-Effect	FY 11 \$	FY 12 \$
Consumer Protection, Dept.	GF - Cost	130,000	130,000
Consumer Protection, Dept.	GF - Revenue Gain	Potential	Potential
Comptroller Misc. Accounts (Fringe Benefits) <sup>1</sup>	GF - Cost	33,325	83,337

Note: GF=General Fund

**Municipal Impact:** None

**Explanation**

The bill results in a cost to the Department of Consumer Protection due to the need for a Drug Control Agent and clerical staff. The total cost for staff and Other Expenses including fringe benefits would be \$163,325 in FY 11 and \$213,337 in FY 12. Staff would be required to review and monitor both in-state and out-of-state pharmaceutical and medical device manufacturers with regard to the provision of gifts, meals, entertainment and other payments to health care providers.

Additionally the bill results in a potential revenue gain to the state as it allows for the imposition of civil penalties of up to \$5,000 for each transaction in violation of the bill's provisions.

**The Out Years**

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation and subject to the number

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<sup>1</sup> The estimated non-pension fringe benefit rate as a percentage of payroll is 26.66% which includes health insurance, social security, Medicare, life insurance, and unemployment compensation. Fringe benefit costs for new positions do not include pension costs as new positions will not impact the state's pension contribution until FY 12 after the next scheduled actuarial valuation.

of violations.

**OLR Bill Analysis****sSB 270*****AN ACT CONCERNING THE PROHIBITION OF CERTAIN GIFTS FROM PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURING COMPANIES TO HEALTH CARE PROVIDERS.*****SUMMARY:**

This bill imposes restrictions and prohibitions on pharmaceutical and medical device manufacturing companies' provision of gifts, meals, entertainment, and other payments to health care providers. It requires these companies to adopt codes of conduct for marketing representatives that comply with these restrictions and prohibitions. The bill also lists certain purposes for which funding or payments from these companies may be used and accepted.

The bill requires each company to (1) have a training program for its representatives on its code and (2) annually provide both a copy of the code and a description of the training program to the Department of Consumer Protection (DCP). It also sets standards for companies' use of prescriber data and permits providers to request that this data not be made available.

The bill prohibits a pharmaceutical or medical device manufacturing company from taking retaliatory actions against an employee, health care provider, job applicant, or others for acting to enforce the bill's provisions.

The bill establishes civil penalties for noncompliance.

EFFECTIVE DATE: July 1, 2010

**DEFINITIONS*****Pharmaceutical or Medical Device Manufacturing Company***

The bill defines "pharmaceutical or medical device manufacturing

company” as an entity (1) engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from natural substances, chemical synthesis, or a combination of these means or (2) directly engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs, biologics, or medical devices. The definition does not include a health care provider; physician practice; home health agency; or a Connecticut-licensed hospital, wholesale drug distributor, or retail pharmacy.

### ***Pharmaceutical or Medical Device Manufacturer Agent***

The bill defines this term as a person, who while employed by or under contract with a pharmaceutical or medical device manufacturing company, engages in detailing, promotional activities, or other marketing of prescription drugs, biologics, or medical devices in this state to any physician; hospital; nursing home; pharmacist; health benefits plan administrator; other health care provider; or other person authorized to prescribe, dispense, or purchase prescription drugs, biologics, or medical devices.

It does not include a (1) licensed pharmacist, physician, or other health care provider with authority to prescribe prescription drugs, biologics, or medical devices acting within the ordinary scope of his or her license; (2) a wholesale drug distributor registered with DCP or a representative of such a distributor who promotes or otherwise markets the distributor’s services in connection with a prescription drug; or (3) a state-licensed retail pharmacy, if the person is not engaging in such practices while employed or under contract with a pharmaceutical or medical device manufacturing company.

### ***Prescription Drugs***

“Prescription drugs” are those upon which the manufacturer or distributor has placed or is required by federal law to place the following or a comparable warning: “Caution: Federal law prohibits dispensing without prescription.”

**Medical Device**

“Medical device” means an instrument, apparatus, implement, machine, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

1. recognized in the official National Formulary or the United States Pharmacopeia or any or their supplements;
2. intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in people or animals; or
3. intended to affect human or animal body structure or function through primary means other than chemical action and is not dependent upon being metabolized to achieve its primary intended purposes.

**Biologic**

A “biologic” is a biological product, as defined in federal law, that is regulated as a drug under the federal Food, Drug, and Cosmetic Act.

**Health Care Provider**

A “health care provider” is (1) a person who prescribes prescription drugs and is licensed to provide health care in this state; (2) a partnership or corporation comprised of such people; or (3) an officer, employee, agent, or contractor of such a person acting in the course and scope of his or her employment, agency, or contract related to, or in support of, providing health care to individuals. The term does not include hospitals and full-time employees and members of board of directors of pharmaceutical or medical device manufacturers.

**MARKETING CODE OF CONDUCT****Adoption of Code**

The bill requires each pharmaceutical or medical device manufacturing company employing or contracting with a pharmaceutical or medical device manufacturer agent to (1) adopt a marketing code of conduct that complies with the bill’s provisions and (2) by July 1, 2011 and annually afterward, provide DCP with (a) a

copy of its code and (b) a description of its program to provide regular training on the code to appropriate employees, including all sales and marketing staff.

The training program must ensure that representatives employed by or acting on behalf of a pharmaceutical or medical device manufacturing company who visit health care providers have sufficient knowledge of the code, general science, and product-specific information to provide accurate and current information consistent with state law and federal Food and Drug Administration (FDA) requirements. The training program must provide for regular assessments of these company representatives' compliance with the bill's provisions and other relevant company policy.

A company's speaker and commercial consultant contracts must require that any health care provider who (1) is a member of a committee that sets formularies or develops clinical guidelines and (2) serves as a speaker or commercial consultant for the company disclose to the committee the existence and nature of that relationship with the company. The disclosure requirement must continue for at least two years after the relationship ends.

### ***Compliance***

By July 1, 2011 and annually afterward, the bill requires each pharmaceutical or medical device manufacturing company employing or contracting with agents to certify to DCP that, to the best of the company's knowledge, it complies with the bill's provisions. It must also provide DCP (1) its policies and procedures for investigating noncompliance, taking corrective action, and reporting noncompliance to the appropriate state authorities and (2) with the name, title, address, telephone number, and electronic mail address of the officer it identifies as responsible for certifying compliance. Each company must also annually, beginning July 1, 2011, certify to DCP that it has external verification procedures in place to monitor compliance with the bill's requirements.

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## **PRESCRIBER DATA USE**

Each pharmaceutical or medical device manufacturing company using prescriber data that is unrelated to a patient's identity to promote communications with health care providers must (1) maintain prescriber data confidentiality and develop policies on its use, (2) educate company employees and agents about these policies and designate an internal contact person to handle data use inquiries, (3) identify appropriate disciplinary actions for misuse, and (4) comply with provider requests that prescriber data not be made available to company sales representatives.

Before using prescriber data for marketing, the bill requires the company to give providers the opportunity to request that their data be withheld from company sales representatives and not be used for marketing.

The bill does not prohibit these companies from using prescriber data to provide important safety and risk information to prescribers of a particular drug or device, conduct research, and comply with FDA mandated risk management plans requiring manufacturers to identify and interact with providers who prescribe certain drugs or devices or track adverse events of marketed drugs or devices.

## **MEALS**

The bill prohibits companies employing or contracting with agents to provide or pay for meals for health care providers that are (1) part of an entertainment or recreational event; (2) offered without an informational presentation made by the agent or without an agent present; (3) offered, consumed, or provided outside of the provider's office or hospital setting; or (4) provided to a provider's spouse or other guest. Meals for providers that otherwise comply with the bill must be modest and occasional.

## **CONTINUING MEDICAL EDUCATION EVENTS, SCIENTIFIC CONFERENCES, AND PROFESSIONAL MEETINGS**

The bill prohibits a pharmaceutical or medical device manufacturing company employing or contracting with an agent from providing financial support for travel, lodging, or other personal

expenses of nonfaculty providers attending any continuing medical education event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event sponsor. (“Nonfaculty” means a provider who does not speak or provide actual and substantive services as a faculty organizer or academic program consultant for such an event, conference or meeting.) In addition the company may not provide:

1. funding to compensate for the time providers spent participating in any event, conference, or professional meeting;
2. payment for meals directly to a provider at any event, conference or meeting, except that a continuing medical education provider or conference or meeting organizer may, at its own discretion, apply a company’s financial support for the event to provide meals for all participants; or
3. sponsorship or payment for continuing medical education or independent medical education that does not meet the Standards for Commercial Support established by the Accreditation Council for Continuing Medical Education or the equivalent commercial support standards of the relevant continuing education accrediting body.

A company must separate its continuing medical education grant-making functions from its sales and marketing divisions. It must not provide any advice or guidance to the continuing medical education provider regarding the content or faculty for a particular program funded by the company.

The bill does not prohibit: (1) compensating or reimbursing a provider serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a continuing medical education event, third-party scientific or educational conference, or professional meeting, if the payment is reasonable based on fair market value and complies with the

standards for commercial support as established by the relevant accreditation entity; (2) sponsoring or paying for any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting, where the payment is made directly to the conference or meeting organizers; or (3) the use of hotel facilities, convention center facilities, or other special event venues for continuing medical education or other third-party scientific, educational, or professional meetings or conferences.

### **ENTERTAINMENT, RECREATION, GRANTS, SCHOLARSHIPS AND OTHER PAYMENTS**

The bill prohibits a pharmaceutical or medical device manufacturing company employing or contracting with agents from providing:

1. entertainment or recreational items of any value, including limited theater, concert, or sporting event tickets, sporting equipment, or leisure or vacation trips, to any health care provider who is not a salaried employee of the company;
2. payments of any kind, including cash or cash equivalents, equity, in-kind or tangible items, including any complimentary items such as pens, coffee mugs, or gift cards to health care providers, either directly or indirectly, except as compensation for bona fide services; or
3. any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice-related items in exchange for prescribing, disbursing, or using prescription drugs, biologics, or medical devices or for a commitment to continue to do so.

“Bona fide services” means an arrangement for services including, research, advisory board participation, collaboration with nonprofit organizations, and presentations at company-sponsored medical education and training. The arrangement must be formalized in a written agreement specifying the services to be provided, based on

their fair market value.

The bill does not prohibit:

1. reasonable compensation for bona fide services or other reasonable out-of-pocket costs a provider incurs directly as a result of performing such services, where the payment is specified in, and paid for under, a written agreement;
2. payment or reimbursement for a provider's reasonable expenses, including travel and lodging-related expenses necessary for technical training on the use of a medical device, if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in the written purchase agreement between the provider and the device vendor;
3. provision of items designed for health care providers' education, such as pamphlets, brochures, and posters, if the value does not exceed \$100 and the items have no value to the provider outside of his or her professional responsibility;
4. the provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical information;
5. the purchase of advertising in peer-reviewed academic, scientific, or clinical journals;
6. the provision of prescription drugs to a health care provider solely and exclusively for use by the provider's patients;
7. the provision of reasonable quantities of medical device demonstration and evaluation units to a health care provider to assess the product's appropriate use and functionality and determine whether or not and when to use or recommend it in the future;
8. the provision of medical text books or anatomical models

- designed for provider education;
9. the provision of price concessions, such as rebates or discounts, in the normal course of business;
  10. the provision of reimbursement information regarding products, including (a) identifying appropriate coverage, coding, or billing of products, (b) procedures for using such products and information in support of accurate and responsible billing to Medicare and other payers, and (c) information designed to offer technical or other support to aid in the appropriate and efficient use or installation of products, except that such technical or other support may not be offered or provided to induce providers to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of such products;
  11. the provision of payments or the provision of free, outpatient prescription drugs to providers for the benefit of low-income people, through an established patient assistance program that meets the criterion for a permissible program under the relevant guidance from the Office of the Inspector General of the U.S. Health and Human Services Department, or is otherwise permitted under applicable federal laws and regulations; or
  12. the provision of a charitable donation that (a) is not provided in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices or for a commitment to continue to do so and (b) does not otherwise violate the bill's provisions.

## **RETALIATORY ACTIONS**

The bill prohibits a pharmaceutical or medical device manufacturing company from discharging, refusing to hire, refusing to serve, or in any way retaliating or taking adverse action against an employee, applicant, health care provider, or covered recipient who has taken any action to further enforcement of the bill's provisions. A

“covered recipient” is a person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the state, including a hospital, nursing home, pharmacist, health benefit plan administrator, or health care provider.

**PENALTIES FOR VIOLATIONS**

A person who knowingly and willfully violates any of the bill’s provisions is subject to a civil fine of up to \$5,000 for each transaction, occurrence, or event that constitutes a violation. Also, the DCP commissioner may assess a civil fine for the same reasons. The attorney general, at the request of DCP, may petition the Superior Court for collection of such fines and any equitable and injunctive relief the court finds appropriate.

**COMMITTEE ACTION**

Public Health Committee

Joint Favorable Substitute

Yea 17      Nay 14      (03/24/2010)